NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMARIN PHARMA, INC., et al., Plaintiffs, v. APOTEX, INC., et al., Defendants.	CIVIL ACTION NO. 14-2550 (MLC)
AMARIN PHARMA, INC., et al., Plaintiffs, v. ROXANE LABORATORIES, INC., Defendant.	CIVIL ACTION NO. 14-2551 (MLC)
AMARIN PHARMA, INC., et al., Plaintiffs, v. DR. REDDY'S LABORATORIES, INC., et al., Defendants.	CIVIL ACTION NO. 14-2760 (MLC)

AMARIN PHARMA, INC., et al., Plaintiffs, v. WATSON LABORATORIES, INC., et al., Defendants.	CIVIL ACTION NO. 14-3259 (MLC)
AMARIN PHARMA, INC., et al., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	CIVIL ACTION NO. 14-3558 (MLC)
AMARIN PHARMA, INC., et al., Plaintiffs, v. ANDRX LABS, LLC, et al., Defendants.	CIVIL ACTION NO. 14-3924 (MLC)

MEMORANDUM OPINION

COOPER, District Judge

The plaintiffs currently hold patents related to a pharmaceutical product known as Vascepa, which "is indicated as an adjunct to diet to reduce triglyceride levels in adult

patients with severe hypertriglyceridemia." (Civil Action No. 14-2550, dkt. 1 at 6.)[1] The plaintiffs alleged in six separate actions that the defendants were infringing those patents by seeking approval to sell generic versions of Vascepa. The Magistrate Judge consolidated the actions for the purposes of discovery ("Consolidated Actions"). (See, e.g., dkt. 42.) This Court presumes the familiarity of the parties with the factual context and procedural history of the Consolidated Actions.

The plaintiffs have now filed a motion pursuant to Federal Rule of Civil Procedure ("Rule") 41(a)(2) to dismiss each complaint without prejudice ("Motion to Dismiss"). (See dkt. 100, dkt. 100-1, dkt. 100-2, dkt. 100-3; see also dkt. 110.) See Fed.R.Civ.P. 41(a)(2). The defendants oppose the Motion to Dismiss. (See dkt. 108, dkt. 108-1, dkt. 108-2; see also dkt. 109, dkt. 109-1.)[2]

This Court will resolve the Motion to Dismiss without oral argument. See L.Civ.R. 78.1(b). This Court, for the following reasons, will grant the Motion to Dismiss.

BACKGROUND

I. Market Exclusivity

A holder of a patent underlying a drug approved by the United States Food and Drug Administration ("FDA") is entitled to a period of market exclusivity of five years if the drug has "no active ingredient (including any ester or salt of the active ingredient) of

[1] All "dkt." cites herein will now refer to the docket entries for Civil Action No. 14-2550.

[2] This Court has cited a proposed order filed under dkt. 109-1, because it contains legal arguments that are not found in the accompanying brief filed under dkt. 109.

which has been approved in any other application." 21 U.S.C. § 355(c)(3)(E)(ii); see also 21 U.S.C. § 355(j)(5)(F)(ii) (stating same). However, the period of market exclusivity is limited to only three years if the drug has "an active ingredient (including any ester or salt of the active ingredient) that has been approved in another application." 21 U.S.C. § 355(c)(3)(E)(iii); see also 21 U.S.C. § 355(j)(5)(F)(iii) (stating same).

II. FDA Determination

The FDA issued a determination ("Determination") that an exclusivity period of three years applied to Vascepa, and thereafter accepted Abbreviated New Drug Applications ("ANDAs") from the defendants to market generic versions of Vascepa. But in subsequent proceedings, the United States District Court for the District of the District of Columbia ("DDC") vacated the Determination, and remanded the matter to the FDA for a new determination on whether an exclusivity period of five years was more appropriate. See Amarin Pharm. Ir. Ltd. v. Food & Drug Admin., 106 F.Supp.3d 196, 206–19 (D.D.C. 2015).

Due to the decision issued by the DDC, the FDA informed the defendants "that FDA has suspended review of Defendants' ANDAs, and, if FDA determines Vascepa qualifies for five-year exclusivity, the exclusivity will bar submission of an ANDA that references Vascepa until at least July 26, 2016." (Dkt. 100-1 at 11.) The FDA, as a result, advised the parties listed in the Consolidated Actions that it "considers [the] ANDA[s] to have been submitted, but not yet received, notwithstanding our previous

communications on th[ese] ANDA[s]. Because [they have] not yet been received, we will not continue to review [the] application[s] until we make a new determination regarding Vascepa's exclusivity status." (Dkt. 100-3 at 9 (emphasis added).)

Watson Laboratories, Inc. ("WLI"), which is a defendant named in one of the Consolidation Actions, appealed from the DDC's decision. The United States Court of Appeals for the District of Columbia Circuit dismissed WLI's appeal for lack of jurisdiction, stating that "[t]he district court order remanding to the FDA is not an appealable final order, because it anticipates further agency action not limited to merely 'ministerial' proceedings." Amarin Pharm. Ir. Ltd. v. Food & Drug Admin., No. 15-5214, slip op. at 1 (D.C. Cir. Dec. 9, 2015). The parties in the Consolidated Actions have not notified this Court whether any further appellate proceedings are being contemplated.[3]

III. Motion to Dismiss

The plaintiffs now file the Motion to Dismiss pursuant to Rule 41(a)(2). The plaintiffs argue that the FDA has decreed that it is not deeming any ANDAs related to Vascepa to be "received," and thus "the statutory act of infringement no longer exists." (Dkt. 100-1 at 5.) As a result, the plaintiffs contend that there is no longer a "case or

[3] In an excess of caution, this Court refrained from addressing the Motion to Dismiss in the event that the parties were to engage in further appellate proceedings. The parties do not appear to have done so.

controversy necessary for the district court to exercise subject matter jurisdiction over," because the "effect of the agency's action is to vitiate the justiciable controversy." (Id.)

The defendants argue in opposition that "[i]t would lead to unnecessary litigation and a waste of judicial resources if the Court were to dismiss the case now," and thus "the Court should deny [the Motion to Dismiss], or at minimum, stay the action and defer its decision until . . . Vascepa's . . . status" is resolved by the FDA. (See dkt. 108 at 6.)

DISCUSSION

The final outcomes of the proceedings before the FDA are in question. But what is not in question is that, at this juncture, the FDA lacks a "received" ANDA related to Vascepa. There is nothing for this Court to adjudicate because the ANDA litigation process cannot proceed without the existence of a "received" ANDA. See 21 U.S.C. § 355(j)(2)(B)(ii)(I) (setting forth the prerequisites for an infringement action brought by a patent holder against an ANDA applicant); see also SB Pharmco P.R. v. Mut. Pharm. Co., 552 F.Supp.2d 500, 502–03 (E.D. Pa. 2008) (stating an "ANDA is not considered filed until the FDA acknowledges receipt," and an ANDA applicant must notify the patent holder "following confirmation from the FDA that the ANDA has been accepted as received" (emphasis added)).[4] Indeed, the FDA has stated that an ANDA "will be reviewed after it is submitted to determine whether the [ANDA] may be received," and that an ANDA is considered "not to have been received" if the patent holder "[i]s entitled

[4] This Court notes that an appeal from this cited case was dismissed pursuant to Federal Rule of Appellate Procedure 42(b). See 318 Fed.Appx. 897 (Fed. Cir. 2008).

to a 5-year period of exclusivity," unless, inter alia, that exclusivity period has elapsed. 21 C.F.R. § 314.101; see also id. (stating "[r]eceipt" signifies that the FDA has made a threshold determination concerning whether an ANDA is ready for review).

The current procedural posture of the Consolidated Actions demonstrates the "important distinction between physically-received ANDAs . . . and officially-received ANDAs." SB Pharmco P.R., 552 F.Supp.2d at 506. Therefore, "the FDA's role in accepting an ANDA for review, so that it is *received* and not merely *delivered*, acts as a safeguard" against premature litigation. Id. at 508 (emphasis in original). Therefore, this Court must grant the Motion to Dismiss because it lacks the authority to adjudicate the Consolidated Actions for want of an ANDA having been deemed as "received" by the FDA. Id. at 511; see also Allergan, Inc. v. Actavis, Inc., No. 14-188 & No. 14-638, 2014 WL 7336692, at *8 (E.D. Tex. Dec. 23, 2014) (granting motion by a holder of a pharmaceutical patent to dismiss its own claims, because "the FDA has not officially 'received' [the] ANDA" from the generic applicants, and thus there was no case or controversy to adjudicate);[5] see also id. at *10–13.

This Court notes that any pending counterclaims in the Consolidated Actions will also be dismissed without prejudice. Any counterclaims have been rendered moot due to the lack of a "received" ANDA herein. Furthermore, the prosecution of any

[5] This Court's review of the Case Management/Electronic Case Files for the United States District Court for the Eastern District of Texas reveals that no appeals have been taken from this cited case.

counterclaims would be without merit until the FDA ultimately determines whether the exclusivity period for Vascepa should be three years or five years.

CONCLUSION

This Court will grant the Motion to Dismiss, and dismiss the complaints in the Consolidated Actions without prejudice. This Court will also dismiss any pending counterclaims in the Consolidated Actions without prejudice. An appropriate order and judgment will follow.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: January 22, 2016